K062966 JAN 12 2007

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K062966

COMPANY/CONTACT PERSON

Seradyn, Inc
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

Establishment registration No: 1836010

Jack Rogers
Manager of Regulatory Affairs
Telephone: (317) 610-3823
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DATE PREPARED

January 8, 2007

DEVICE NAME

Trade Name:	QMS® Lamotrigine
Common Name:	Homogeneous Particle-Enhanced Turbidimetric Immunoassay
Device Classification:	21 CFR 862.3350 Diphenylhydantoin Test System; Class II

INTENDED USE

The QMS® Lamotrigine assay is intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers.

Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine.

The QMS® Lamotrigine Calibrator set is intended for use in calibration of the QMS Lamotrigine assay.

The QMS® Lamotrigine Control set is intended for use in quality control of the QMS Lamotrigine assay.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

QMS® Zonisamide assay (K051211)

DESCRIPTION OF DEVICE

The QMS® Lamotrigine assay system is a homogeneous assay utilizing particle agglutination technology and is based on the competitive binding principle.

The assay consists of reagents R1: anti-Lamotrigine sheep polyclonal antibody and R2: Lamotrigine-coated microparticles. A six-level set of QMS® Lamotrigine Calibrators (A through F) is used to calibrate the assay. A three-level set of QMS® Lamotrigine Controls (1 through 3) is used for quality control of the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device QMS® Lamotrigine	**Predicate** QMS® Zonisamide
Intended Use	The QMS Lamotrigine assay is intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers.	The QMS Zonisamide assay is intended for the quantitative determination of zonisamide in human serum or plasma on automated clinical chemistry analyzers.
Indications for Use	Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine.	Zonisamide concentrations can be used as an aid in management of patients treated with zonisamide.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)
Reagent Components	Two (2) reagent system: • Anti-Lamotrigine Antibody Reagent (R1) in buffers containing stabilizers with sodium azide • Lamotrigine-coated Microparticle Reagent (R2) in buffer containing stabilizers with sodium azide	Two (2) reagent system: • Anti-Zonisamide Antibody Reagent (R1) in buffers containing stabilizers with sodium azide • Zonisamide-coated Microparticle Reagent (R2) in buffer containing stabilizers with sodium azide
Calibration	QMS Lamotrigine Calibrators – six levels	QMS Zonisamide Calibrators – six levels
Quality Control	QMS Lamotrigine Controls – three levels	QMS Zonisamide Controls – three levels

SUMMARY OF CLINICAL TESTING

Accuracy and Linearity

Accuracy and linearity were determined by a study based on the NCCLS guideline *EP6: Evaluation of the Linearity of Quantitative Measurement.*

Sensitivity

The Functional Sensitivity or Limit of Quantitation (LOQ) of the assay was determined to be 2.0 µg/mL.

Assay Range

Based on the Accuracy, Linearity, and Sensitivity (LDD and LOQ) data, the package insert claim for the reportable range for the assay is 2.0 to 40.0 µg/mL.

Method Comparison

Correlation studies were conducted using NCCLS Guideline *EP9: Method Comparison and Bias Estimation Using Patient Samples* as a guideline to compare accuracy of recovery of Lamotrigine in serum and plasma assayed by the QMS® Lamotrigine assay to an HPLC reference method.

Precision

A precision study was performed using the National Committee for Clinical Laboratory Standards (NCCLS) guideline *EP5: Evaluation of Precision Performance of Clinical Chemistry Devices.*

Specificity

There is one pharmacologically inactive metabolite, N-2 glucuronide. Three other minor metabolites, N-5 glucuronide, N-2 oxide, and N-2 methyl have been proposed in literature. Testing results indicated that for N-2 oxide there is cross-reactivity, however, this metabolite is present in human serum in only very minor concentrations. No studies to date have been able to quantify the N-2 oxide metabolite in serum due to its extremely low concentration. Results for the other metabolites indicated that there is no significant cross-reactivity.

Interferences

Interference studies were conducted using NCCLS Guideline *EP7: Interference Testing in Clinical Chemistry*. The results of the study indicated that of 26 drugs tested, none showed cross-reactivity in the QMS lamotrigine assay system.

CONCLUSION

As summarized above, the QMS® Lamotrigine assay is substantially equivalent to the QMS Zonisamide assay. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUN 09 2010

Seradyn Inc.
C/O Mr. Jack Rogers
7998 Georgetown Road, Suite 100
Indiannapolis, IN 46268

Re: k062966
Trade/Device Name: QMS® Lamotrigine
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin Test System
Regulatory Class: Class II
Product Code: ORH, LAS, DLJ
Dated: December 20, 2006
Received: December 21, 2006

Dear Mr. Rogers:

This letter corrects our substantially equivalent letter of January 12, 2007.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062966

Device Name: QMS® Lamotrigine

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062966